Remarks

The Interview

Applicants and the undersigned greatly appreciate the opportunity to speak to the examiner and his supervisor regarding the invention and discuss proposed claim amendments. As discussed at the interview, Dr. Goldstein has been a practicing dermatologist for many years. In the course of his treatment of patients, he has observed that many mid and high potency steroids cause serious side effects including thinning of the skin, hypopigmentation, and striar destrae, which may be as significant of a problem as the presenting condition since fungal conditions take up to four weeks to respond to treatment. Indeed, the American Academy of Pediatrics states that many of these steroids, especially the high and mid-level steroidal antiinflammatories, should not be used in children due to the risk of side effects. During this extended period of treatment, the patient have to put up with irritation, redness and itching. Therefore there is a need for a composition that is both effective but safe, with minimal side effects.

Based on his extensive clinical experience, Dr. Goldstein has discovered that low and low-mid potency non-fluorinated steroidal antiinflammatories can be combined with an antifungal to provide a safe and effective treatment with minimal side effects. He presented

photos of one case study wherein the patient had presented with scaly red and inflamed, raised areas of skin infected wtih inflammatory tinea. This patient had previously been treated with a variety of medications, none effective. Dr. Goldstein treated the patient with a topical cream containing 0.05% desonide and 1% clotrimazole. Within a few days, the redness and swelling had disappeared, leaving skin looking almost normal in the photographs.

Rejection under 35 U.S.C. 112

Claim 14 was rejected under 35 U.S.C. 112, as indefinite. This rejection is respectfully traversed if applied to the amended claim which deletes the objected to phrase.

Rejections under 35 U.S.C. 102 and 103

Claims 1-10, 13-16 were rejected under 35 U.S.C. 102 as disclosed by U. S. Patent No. 6,444,647 to Robinson, et al. Claims 1-5, 7-13 were rejected under 35 U.S.C. 102 as disclosed by U. S. Patent No. 6,075,056 to Quigley, et al. Claims 1-9, 13, 14, 16 were rejected under 35 U.S.C. 102 as disclosed by U. S. Patent No. 5,686,089 to Mitra, et al. Claims 1-10 were rejected under 35 U.S.C. 102 as disclosed by U. S. Patent No. 5,219,877 to Shah, et al.

Claim 15 was rejected under 35 U.S.C. § 103 (a) as obvious over U. S. Patent No. 5,686,089 to Mitra, et al.

These rejections are respectfully traversed if applied to the amended claims.

As discussed at the interview, the invention is the selection of the class of non-halogenated steroidal antiinflammatories that can be used in combination with antifungal medication to treat a patient with efficacy but with minimal side effects. The claims have been amended as discussed at the interview to define the claimed composition and method as follows:

A topical formulation (support is found at page 2, line 7)

Non-halogenated low or mid-potency steroidal antiinflammatories (page 2, lines 7-10; page 3, lines 19-21) (See attached printout from the National Psoriasis Foundation website showing the different categories and which products lie within each)

having a higher potency than 1 wt% hydrocortisone (page 5, lines 13-15)

in a concentration between 0.01 wt% and 5.0 wt% (page 4, lines 15-16)

The data presented at the interview demonstrated the unexpected efficacy and lack of side effects of one non-halogenated steroidal antiinflammatory, desonide, in combination with an antifungal. Additional data showing the same unexpected efficacy and lack of side effects for other members of the claimed class of non-

halogenated steroidal antiinflammatories will be submitted shortly. Other members of the claimed class that have been shown to produce results comparable to a topical cream containing 0.05% desonide and 1% clotrimazole are:

Clotrimazole 1% cream with aclometasone dipropionate 0.05% cream applied twice daily.

Oxicanozole cream 1% with Hydrocortisone cream 2½% applied twice daily.

Econazole cream 1% with fluocinalone acetonide cream 0.01% applied twice daily

Econazole cream 1% with aclometasone dipropionate 0.05%, applied twice daily.

U.S. Patent No. 6,075,056 to Quigley, et al. discloses the use of steroidal antiinflammatories with a wide range of potencies (see col. 2, lines 7-10; col 4, line 55 to col. 5, line 51). There is no recognition that the potency of the steroidal antiinflammatory is the cause of the side effects and can be eliminated not by changing the carrier as suggested by Quigley but by selecting a narrow class of steroidal antiinflammatories.

U.S. Patent No. 5,219,877 to Shah, et al. describes a gel formulation for topical aministration including an imidazole antifungal in combination with a mid-potency steroidal

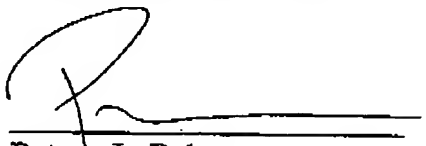
antiinflammatory. As described at col. 4, lines 3-16, this class of compounds is not within the claimed class of low and low-mid potency steroidal antiinflammatories.

U.S. Patent No. 5,686,089 to Mitra et al. describes treatment with a topical formulation to treat infections with an antimicrobial agent (col. 3, lines 1-49) which can include an antiinflammatory (col. 6, line 65 to col. 7, line 28). There is no teaching of the claimed class of steroidal antiinflammatories, the problems with treatment with mid and high potency antiinflammatories, nor that one should select low or low-mid potency steroidal antiinflammatories.

U.S. patent No. 6,444,647 to Robinson, et al. describes a skin care composition containing as active ingredients a vitamin B3 comopund, farnesol, phytantriol or mixtures thereof, and a carrier. There is nothing teaching one to select low to low-mid potency non-halogenated steroidal antiinflammatories for treatment of skin conditions.

In summary, applicants have demonstrated that the claimed combination unexpected provides efficacy and safety, which is neither recognized by nor obvious from the prior art. Allowance of all claims as amended is therefore earnestly solicited.

Respectfully submitted,



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Topical steroids

Potencies of topical steroids

Topical steroid medications come in various strengths, ranging from very strong, or superpotent (very weak, or least potent (Class 7). Once a person has stopped responding to a steroid of a par strength or potency, it is unlikely he or she will respond to any brand of steroid at an equal or low unless an extended period of time has elapsed. The potency chart below provides the potencies of steroid medications used to treat psoriasis.

Generally, the stronger the steroid, the more effective it is in clearing psoriasis, but the risk of sid also greater. The base, or formulation, of a steroid medication can also influence how much med penetrates the tissue. Steroids come in a variety of bases, such as creams, ointments, gels, spra solutions, lotions, foam and tape.

Potency chart

The following potency chart categorizes brand-name topical steroid medications along with the n corresponding generic drug. The list positions these medications according to their potency. The be comprehensive.

BRAND NAME	GENERIC NAME
CLASS 1 - Superpotent	
Clobex Lotion, 0.05%	Clobetasol propionate
Cormax Cream/Solution, 0.05%	Clobetasol propionate
Diprolene Gel/Ointment, 0.05%	Betamethasone dipropionate
Olux Foam, 0.05%	Clobetasol propionate
Psorcon Ointment, 0.05%	Diflorasone diacetate
Temovate Cream/Ointment/Solution, 0.05%	Clobetasol propionate
Ultravate Cream/Ointment, 0.05%	Halobetasol propionate
CLASS 2 - Potent	
Cyclocort Ointment, 0.1%	Amcinonide
Diprolene Cream AF, 0.05%	Betamethasone dipropionate
Diprosone Ointment, 0.05%	Betamethasone dipropionate
Elocon Ointment, 0.1%	Mometasone furoate
Florone Ointment, 0.05%	Diflorasone diacetate
Halog Ointment/Cream, 0.1%	Halcinonide

Lidex Cream/Gel/Ointment, 0.05%	Fluocinonide
Maxiflor Ointment, 0.05%	Diflorasone diacetate
Maxivate Ointment, 0.05%	Betamethasone dipropionate
Psorcon Cream 0.05%	Diflorasone diacetate
Topicort Cream/Ointment, 0.25%	Desoximetasone
Topicort Gel, 0.05%	Desoximetasone
CLASS 3 - Upper Mid-Strength	
Aristocort A Ointment, 0.1%	Triamcinolone acetonide
Cutivate Ointment, 0.005%	Fluticasone propionate
Cyclocort Cream/Lotion, 0.1%	Amcinonide
Diprosone Cream, 0.05%	Betamethasone dipropionate
Florone Cream, 0.05%	Diflorasone diacetate
Lidex-E Cream, 0.05%	Fluocinonide
Luxiq Foam, 0.12%	Betamethasone valerate
Maxiflor Cream, 0.05%	Diflorasone diacetate
Maxivate Cream/Lotion, 0.05%	Betamethasone dipropionate
Topicort Cream, 0.05%	Desoximetasone
Valisone Ointment, 0.1%	Betamethasone valerate
CLASS 4 - Mid-Strength	
Aristocort Cream, 0.1%	Triamcinolone acetonide
Cordran Ointment, 0.05%	Flurandrenolide
Derma-Smoothe/FS Oil, 0.01%	Fluocinolone acetonide
Elocon Cream, 0.1%	Mometasone furoate
Kenalog Cream/Ointment/Spray, 0.1%	Triamcinolone acetonide
Synalar Ointment, 0.025%	Fluocinolone acetonide
Uticort Gel, 0.025%	Betamethasone benzoate
Westcort Ointment, 0.2%	Hydrocortisone valerate
CLASS 5 - Lower Mid-Strength	
Cordran Cream/Lotion/Tape, 0.05%	Flurandrenolide
Cutivate Cream, 0.05%	Fluticasone propionate
DermAtop Cream, 0.1%	Prednicarbate
DesOwen Ointment, 0.05%	Desonide ✓
Diprosone Lotion, 0.05%	Betamethasone dipropionate
Kenalog Lotion, 0.1%	Triamcinolone acetonide
Locoid Cream, 0.1%	Hydrocortisone butyrate ✓

Pandel Cream 0.1%	Hydrocortisone probutate
Synalar Cream, 0.025%	Fluocinolone acetonide
Uticort Cream/Lotion, 0.025%	Betamethasone benzoate
Valisone Cream/Ointment, 0.1%	Betamethasone valerate
Westcort Cream, 0.2%	Hydrocortisone valerate
CLASS 6 - Mild	
Aclovate Cream/Ointment, 0.05%	Alclometasone dipropionate
DesOwen Cream, 0.05%	Desonide
Synalar Cream/Solution, 0.01%	Fluocinolone acetonide
Tridesilon Cream, 0.05%	Desonide
Valisone Lotion, 0.1%	Betamethasone valerate
CLASS 7 - Least Potent	
Topicals with hydrocortisone, dexamethasone, methylprednisolone and prednisolone	

Updated July 2004

Related links

- Topical steroids
- Internal use of steroids
- Methods of using topical steroids
- Side effects of topical steroids
- Tips for using topical steroids